



DEPARTMENT OF TRANSPORTATION

[4910-EX-P]

Federal Motor Carrier Safety Administration

49 CFR Part 391

Federal Railroad Administration

49 CFR Parts 240 and 242

[Docket Numbers FMCSA–2015–0419 and FRA–2015–0111]

RIN 2126 –AB88 and 2130-AC52

Evaluation of Safety Sensitive Personnel for Moderate-to-Severe Obstructive Sleep Apnea

ACTION: Advance notice of proposed rulemaking; withdrawal.

SUMMARY: The Federal Motor Carrier Safety Administration (FMCSA) and Federal Railroad Administration (FRA) (collectively, the Agencies) withdraw the March 10, 2016, advance notice of proposed rulemaking (ANPRM) concerning the prevalence of moderate-to-severe obstructive sleep apnea (OSA) among individuals occupying safety sensitive positions in highway and rail transportation, and its potential consequences for the safety of highway and rail transportation. The Agencies have determined not to issue a notice of proposed rulemaking at this time.

DATES: As of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER] the ANPRM published on March 10, 2016, at 81 FR 12642 is withdrawn.

FOR FURTHER INFORMATION CONTACT:

FMCSA: Ms. Christine Hydock, Chief of the Medical Programs Division, FMCSA, 1200 New Jersey Ave, SE., Washington, DC 20590-0001, by telephone at 202-366-4001, or by email at fmcsamedical@dot.gov.

FRA: Dr. Amanda Emo, Fatigue Program Manager, Risk Reduction Program Division, Office of Safety Analysis, FRA, 1200 New Jersey Avenue, S.E., Washington, DC 20590-0001, by telephone at 202-281-0695, or by email at amanda.emo@dot.gov.

If you have questions about viewing or submitting material to the docket, contact Docket Services, telephone 202-493-0402.

SUPPLEMENTARY INFORMATION:

Background

Based on the potential severity of OSA-related transportation incidents and crashes/accidents, and the varied, non-regulatory, OSA-related actions the Department's Operating Administrations have taken to date, the Agencies issued a joint ANPRM to consider regulatory action to ensure consistency in addressing the risk of OSA among transportation workers with safety sensitive duties (81 FR 12642, March 10, 2016). The Agencies sought information from interested parties regarding OSA to better inform their decision on whether to take regulatory action and, if so, how to craft the most effective and efficient regulations to address the potential safety risks associated with untreated OSA.

The information requested in the ANPRM seemed to be necessary to help the Agencies quantify the potential economic benefits and costs of adopting standards to assess risks associated with motor carrier and rail transportation workers in safety sensitive positions diagnosed with OSA. To gather relevant data, the Agencies posed a series of questions addressing the following matters:

- Whether OSA is a problem among individuals occupying safety sensitive positions in highway and rail transportation;

- Cost and benefits of regulatory actions that address the safety risks associated with motor carrier and rail transportation workers in safety sensitive positions who have OSA;
- Qualifications and restrictions for medical personnel; and
- Treatment effectiveness.

The Agencies also sought information at three listening sessions in May 2016, and extended the comment period by thirty days to review the results from the American Transportation Research Institute (ATRI) Commercial Driver Survey on Sleep Apnea Issues (<http://atri-online.org/2016/04/14/atri-launches-commercial-driver-survey-on-sleep-apnea-issues/>). The Agencies received more than 700 comments from individuals, medical professionals, labor groups, and transportation industry stakeholders. The Agencies also received comments from the National Transportation Safety Board and three members of Congress, the Honorable Anna Eshoo, the Honorable Sam Farr, and the Honorable Michael M. Honda.

The Agencies' Decision

OSA remains an on-going concern for the Agencies and the motor carrier and railroad industries because it can cause unintended sleep episodes and resulting deficits in attention, concentration, situational awareness, and memory, thus reducing the capacity to safely respond to hazards when performing safety sensitive duties. The Agencies received valuable information in response to the ANPRM and a series of public listening sessions in May 2016. The Agencies believe that current safety programs and FRA's rulemaking addressing fatigue risk management are the appropriate avenues to address OSA.

FMCSA will consider an update to its January 2015 "Bulletin to Medical

Examiners and Training Organizations Regarding Obstructive Sleep Apnea” regarding the physical qualifications standard and related advisory criteria concerning respiratory dysfunction, specifically how the standard applies to drivers who may have OSA. The Agency would use the updated August 2016 Medical Review Board¹ recommendations as a basis for updating the bulletin. On August 22-23, 2016, the MRB met in public meetings to deliberate on *Medical Review Board Task 16-1* regarding public comments from medical professionals and associations on the FMCSA’s and FRA’s ANPRM on obstructive sleep apnea. FMCSA tasked the MRB with reviewing and analyzing all ANPRM comments from medical professionals and associations and to identify factors the Agency should consider regarding making decisions about the next step in the OSA rulemaking. FMCSA also requested that the MRB review its previous February 2012 report on OSA from the MRB and Motor Carrier Safety Advisory Committee (MCSAC). The MRB’s February 2012 recommendations formed the basis of their August 2016 recommendations. In scenarios where medical examiners may inappropriately screen and refer drivers for diagnostic testing based on single criteria, the MRB’s 2016 recommendations provide objective criteria for identifying drivers who may be at greater risk for OSA. And, as was the case with the 2015 bulletin, the purpose of any action updating the bulletin is to ensure that medical examiners fully understand their role in screening drivers for OSA, identifying drivers at the greatest risk of having OSA, and refer only those individuals to a sleep specialist for testing. The Agency reminds medical examiners that there are no FMCSA rules or other regulatory guidance beyond what is

¹ <https://www.fmcsa.dot.gov/advisory-committees/mcsac/mrb-task-16-01-letter-report>. A copy of the MRB recommendations is included in this rulemaking docket.

referenced in this paragraph above with guidelines for screening, diagnosis, and treatment of OSA in CMV drivers. Medical certification determinations for such drivers are made by the examiners based on the examiner's medical judgment rather than a Federal regulation or requirement.

In addition, FMCSA will continue to recommend that drivers and their employers use the North American Fatigue Management Program (NAFMP) (<http://www.nafmp.org/index.php?lang=en>). The NAFMP is a voluntary, fully interactive web-based educational and training program developed to provide both truck and bus commercial vehicle drivers and carriers and others in the supply chain with an awareness of the factors contributing to fatigue and its impact on performance. Guidance on health and wellness, time management, vehicle technologies and scheduling best-practices provide effective mitigation strategies to address fatigue while maintaining a healthy and productive work/life balance. Module 8 of the program, Driver Sleep Disorders Management, includes an extensive discussion of OSA. [The training materials may be downloaded at http://www.nafmp.org/index.php?option=com_content&view=article&id=14:downloads&catid=26&lang=en&Itemid=115.]

On September 21, 2004, FRA issued Safety Advisory 2004-04 to alert the railroad industry, and especially those employees with safety sensitive duties, to the danger associated with degradation of performance resulting from undiagnosed or unsuccessfully treated sleep disorders (69 FR 58995, Oct. 1, 2004). That Safety Advisory set forth recommended actions regarding OSA, which FRA reiterated in Safety Advisory 2016-03 (81 FR 87649, Dec. 5, 2016). Additionally, FRA is aware several railroads are

implementing OSA identification and treatment programs. FRA anticipates these programs will identify best practices for OSA screening, diagnosis, treatment, and mitigation. These programs will help identify the current and future needs of the industry, potential costs, and help define FRA's role in addressing OSA in the railroad industry. In addition, under the Rail Safety Improvement Act of 2008 (RSIA), railroads must establish a fatigue management plan as part of their Risk Reduction Program (RRP) or System Safety Program (SSP) (49 U.S.C. 20156(f)). RSIA requires a railroad to consider the need to include in its fatigue management plan "opportunities for identification, diagnosis, and treatment of any medical condition that may affect alertness or fatigue, including sleep disorders." (Id. at section 20156(f)(3)(B).) While RSIA does not address OSA by name, FRA believes railroads will consider OSA when addressing medical conditions that affect alertness under a railroad's fatigue risk management plan as part of an RRP or SSP. FRA will continue to monitor railroads' voluntary OSA programs, as well as the implementation of fatigue risk management plans, as part of an RRP or SSP.

Based on the foregoing reasons, the Agencies withdraw the March 2016 ANPRM

entitled “Evaluation of Safety Sensitive Personnel for Moderate-to-Severe Obstructive Sleep Apnea.” If FRA or FMCSA determines further action to be necessary, it will consider regulatory action.

Issued under the authority of delegations in 49 CFR 1.87(f) and (i) and 49 CFR 1.89(a), respectively: July 31, 2017

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